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ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR 2001-1028 5816 07/25/2002 Marinus Gerardus Cornelis Kivits 10/089,995 **EXAMINER** 03/17/2006 7590 466 YOUNG & THOMPSON SHAFER, SHULAMITH H 745 SOUTH 23RD STREET ART UNIT PAPER NUMBER 2ND FLOOR ARLINGTON, VA 22202 1647

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|   |  | Application No.  | Applicant(s)  |  |
|---|--|--|---------------|--|
| Office Action Summary   |  | 10/089,995   | KIVITS ET AL. |  |
|   |  | Examiner   | Art Unit      |  |
|   |  | Shulamith H. Shafer, Ph.D.   | 1647          |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |  |  |               |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |  |  |               |  |
| Status  |  |  |               |  |
| 2a) <u></u>   | Responsive to communication(s) filed on <u>25 July 2002 and 02 August 2004</u> .  This action is <b>FINAL</b> . 2b) This action is non-final.  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |               |  |
| Disposition of Claims   |  |  |               |  |
| 5)<br>6)<br>7)  | 4)  Claim(s) 1-15 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5)  Claim(s) is/are allowed.  6)  Claim(s) is/are rejected.  7)  Claim(s) is/are objected to.  8)  Claim(s) 1-15 are subject to restriction and/or election requirement.   |  |               |  |
| Application Papers  |  |  |               |  |
| 9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |  |  |               |  |
| Priority under 35 U.S.C. § 119  |  |  |               |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |  |  |               |  |
| Attachment(s)   |  |  |               |  |
| 2) Noti 3) Info   | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: |               |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7 in part, drawn to a process for extracting transforming growth factor  $\beta$  (TGF- $\beta$ ) from a milk product.

Group II, claim(s) 1-7 in part, drawn to a process for extracting insulin-like growth factor 1 (IGF-1) from a milk product.

Group III, claim(s) 8-10, 14 in part, 15 in part, drawn to products which contain TGF-β in the substantial absence of IGF-1.

Group IV, claim(s) 11-13, 14 in part, 15 in part, drawn to products which contain IF-1 in the substantial absence of TGF-  $\beta$ .

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475 states: The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

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The first claim of the instant invention is drawn to a method for extracting two different growth factors, TGF-β and IGF-1, from a milk product. A method for extracting and purifying each of these proteins represents a separate patentable invention. Therefore, since the first claimed invention does not have a single technical feature, it cannot share a special technical feature with the other claimed inventions.

Furthermore, Groups II-IV define separate contributions to the art.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

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claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shulamith H. Shafer, Ph.D. whose telephone number is 571-272-3332. The examiner can normally be reached on Monday through Friday, 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D. can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHS

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